No. 80-680

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

JACK WERNER,
Petitioner,

v.

THE UPJOHN COMPANY, INC. AND
RALPH J. CARBO, JR., M.D.,
Respondents,

PETITIONER'S REPLY BRIEF ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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ARGUMENT

I.

THIS CASE PRESENTS AN INTERCIRCUIT CONFLICT.

Respondents argue that the decision below is not in conflict with any other Federal circuit decisions concern-

ing Rule 407 of the Federal Rules of Evidence. This is somewhat surprising since the Fourth Circuit perceived the conflict: it pointed out that "the courts have split" on the applicability of Rule 407 in strict liability cases, and it cited *Robbins v. Farmers Union Grain Terminal Assn.*, 552 F.2d 788 (8th Cir. 1977) as a decision of one of the courts which "would admit the evidence" (P. App. A. p. 12a).

Respondents contend that the rulings of the Fourth Circuit are dicta because (a) they are merely for the guidance of the District Judge on retrial and (b) the Fourth Circuit expressed doubt as to whether the admissibility of the evidence on the grounds urged by Petitioner were properly before it. The Fourth Circuit, however, has stated its holding: "We *hold* that the district court erred *in admitting the subsequent warning into evidence.*" (P. App. A. p. 2a, Emphasis supplied). Moreover, since the verdict was in Petitioner's favor on several special interrogatories (App. 51-2) the Fourth Circuit had to and did consider the various grounds for admissibility raised by Petitioner in order to hold that any possible error in admitting the evidence was not harmless.[1]

The decision of the Fourth Circuit is binding on the district judge on retrial and will foreclose petitioner from offering the evidence of the subsequent warning on any ground. The Fourth Circuit decision has as much "bite," and is as ripe for review by this court, as a ruling on evidence can be; and it should be reviewed in order to

[1] Thus, the jury found for plaintiff on the express warranty issue. This finding is independent of any issue of negligence or culpable conduct, and if the evidence of the subsequent warning was admissible to prove breach of warranty (Petition pp. 23-4), the decision below is wrong. Respondents simply do not — because, it is submitted, they cannot — address petitioner's argument on this point.

prevent the injustice which will occur in civil trials in that Circuit if, as Petitioner contends, the decision is wrong.[2]

The decision, moreover, is no less a holding because it also rested on an "alternate ground" of alleged inconsistency of verdict. It is well settled that when a decision is explicitly rested on alternate grounds,[3] both grounds are holding and neither is dictum. *Woods v. Interstate Realty Co.*, 337 U.S. 535 (1948); *Richmond Screw Anchor Co. v. U.S.*, 275 U.S. 531 (1928); *U.S. v. Title Ins. & Trust Co.*, 265 U.S. 472 (1924).

Respondents contend that the Fourth Circuit felt it was "arguable" that the possible admissibility of the evidence on grounds not raised at trial (Resp. Upjohn Br. p. 16) would not prevent reversal. The simple answer is that the Fourth Circuit's doubts did not prevent it from "examining" "plaintiff's other arguments for admitting the evidence" (P. App. 11 a) and holding the evidence inadmissible on any ground. Furthermore, it has been settled for well over a century that where the judgment of the trial court was in favor of Petitioner, that judgment may be supported on appeal upon any ground apparent from the

[2] Respondent Carbo seems to think there is no lack of ripeness for review since he asks that the writ of certiorari issue so that the judgment and opinion below may be affirmed. The petition for certiorari, of course, was not a definitive brief on the merits, but merely an attempt to show that the questions presented are substantial and should receive plenary review.

[3] Respondents simply do not, again because, it is submitted, they cannot, point to any error or fallacy in Petitioner's demonstration that the verdicts on the negligence and strict liability issues are fully consistent (Petition pp. 11-12, 27 n.11). The very recent case of *Hasson v. Ford Motor Co.*, 19 Cal. 3d 530, 138 Cal. Reptr. 705, 564 P.2d 857 (1980) also supports Petitioner's argument on this point. The court held that there was no inconsistency between a verdict for a manufacturer on strict liability where at the time of sale the product was deemed not defective and against the manufacturer for negligence in failing to warn after the sale.

record which renders it correct, whether that ground was relied on at trial or not. See *California Bankers Ass'n. v. Shultz*, 416 U.S. 21, 71 (1924); *Erwin v. Lowry* 7 How. (U.S.) 172 (1849).

Next, Respondents argue that the Federal circuit decisions which the Fourth Circuit explicitly "decline[d] the invitation to follow" (P. App. 17 a) are not really in conflict with the decision below. The single most noteworthy point about this argument is that it does not even mention *Robbins v. Farmers Union Grain Terminal Assn., supra*, which held that a subsequent warning was admissible to prove causation (Petition pp. 18-20), while the Fourth Circuit has held to the contrary (P. App. 17 a).

Despite Respondents' attempt to make nice distinctions based on a hypertechnical view of the theory of precedent and of the decisions they seek to distinguish,[4] it is clear

[4] E.g., Respondents seek to distinguish *Lolie v. Ohio Brass Co.*, 502 F.2d 741, (7th Cir. 1974) as having been decided before the effective date of the Federal Rules of Evidence, (Resp. Upjohn Br. p. 25) but *Lolie* construed Rule 407 as then proposed, which was identical in language to the rule as finally adopted (Petition p. 14). Similarly, Respondents seek to distinguish *Robbins* because *Robbins* dealt with the adequacy of warning and instructions for cattle feed rather than with a prescription drug which is "unavoidably unsafe" within the meaning of Comment k of Section 402A of the *Restatement* (Resp. Upjohn Br., p. 20). Respondents contend that knowledge of the Defendant was not an element of strict liability under *Robbins*, but it is in a drug strict liability case. However, the drug is "unavoidably unsafe" only when it is used for proper indications. In the present case, Upjohn admitted that the risk-benefit ratio did not justify the use of Cleocin for any infections other than serious infections. (App. 312, 255). It was not *unavoidably* unsafe when used orally for minor infections (App. 312, 522, PX 46). It was avoidably unsafe because it should never have been promoted for such use. Restatement of Torts (2d) § 402A, Comment *k* deals with drugs whose marketing is justified where the risk of the condition being treated outweighs the risk of complications due to the unavoidably unsafe character of the drug. This is not the situation here. The cases cited at Petition

that the decision of the Fourth Circuit represents a sharp departure in attitude and philosophy from the decisions in other circuits on Rule 407. The result in the real world, unless this Court intervenes, will be disparate rulings and unequal treatment for litigants in different circuits — the very opposite of the "uniform code of evidence in the Federal Courts," which it was the purpose of the Federal Rules to achieve (see H. Rep. No. 93-650, 28 USCA Federal Rules of Evidence p. 823).

II.

THE QUESTIONS PRESENTED ARE IMPORTANT AND DESERVE REVIEW.

Rule 407 includes exceptions which have built into the rule a degree of tension and potential for confusion. See *Weinstein's Evidence* (1977) pp. 407-9 to 407-12 pointing out the uncertainty created by the many exceptions to the rule, and arguing that Rule 407, even where applicable has only "marginal justification". Judge Weinstein points out that the assumption in today's world that a defendant manufacturer of a consumer product will not take remedial measures unless assured that they will not be admitted in evidence is "absurd" because of the greater

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pp. 16-17, apply. As stated in *Hamilton v. Hardy*, 549 P.2d 1099 (Colo. App. 1976), certiorari denied by Colo. Sup. Ct.: in a strict liability case, the issue is whether the failure to give adequate warning rendered the product *unreasonably* dangerous, without regard to the reasonableness of the manufacturer's conduct in regard to the warning when judged by negligence standards. There is no difference between the Maryland law of strict liability and the law in the cases Respondents seek to distinguish. The Restatement of Torts (2d) § 402A has established a doctrine of strict liability generally adopted and no Maryland case supports Respondents contention that the Maryland view of strict liability is not the same as that of the jurisdictions with which the Fourth Circuit is in conflict. *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971), cited at Petition, p. 17, supports the view urged by Petitioner that in strict liability cases the adequacy of a drug warning is not governed by negligence principles.

threat of lawsuits if he does not make the change. Moreover, because many state courts, such as Maryland, will admit the evidence, "it is unlikely that any person whose conduct might be affected by the rule would be guided by the federal rule of exclusion."

For these reasons, as well as those set forth in the Petition, it is essential that the trial bar and the lower Federal Courts have authoritative guidelines as to the proper scope and application of this controversial rule.

III.

RESPONDENTS' STATEMENT OF FACTS DOES NOT PROVIDE A FAIR PERSPECTIVE ON THE FACTUAL BACKGROUND OF THIS CASE.

Respondents, in conclusory fashion, attack petitioner's statement of facts as "biased and inaccurate." (Resp. Upjohn Br. p. 1) They do not, however, point to a single quotation, documentary reference, or statement of a witness in Petitioner's statement of facts which is inaccurate in the slightest respect.[5] Instead, they "restate the facts" relying heavily on self-serving statements of some of their witnesses, which are often contrary to Respondents' own documents and in conflict with the testimony of other witnesses. As to certain factual matters not covered in the Petition and raised in Respondents' briefs, the following specific comments are appropriate:

a. The clinical studies of the 5,500 patients (Resp. Upjohn Br. p. 1) would not necessarily show any psuedomembranous colitis since the patients were not

[5] Particularly noteworthy is the failure of Respondents' Brief to advert to any of Upjohn's own documents relating to the number of Cleocin deaths Upjohn was aware of in 1974 and the fact that the FDA, which had only the information Upjohn gave it, was not supplied with the true number. See PX 37, PX 51, PX 52, PX 53, PX 60, App. 586-93.

sigmoidoscoped, which is the only definitive way of demonstrating this illness (App. 168, 184, 264).

b. Dr. Tedesco did not find psuedomembranous colitis to be "benign and self-limiting" in the normal course. The only reason there were no serious complications in his study was that the patients were in the hospital and he monitored them by sigmoidoscopy and treated them at the first signs of PMC before the disease had a chance to develop through its normal course. (App. 189-90, 220-21). At its very earliest stages, if then diagnosed, PMC is treatable with good results, and does not have the same serious consequences as when treatment is not begun until later. Upjohn's trial counsel recognized the distinction in his argument to the jury at App. 459, where he said: "We know, from the testimony of the two gastroenterologists in the case, who treat this kind of problem, that early diagnosis and prompt treatment is essential if the patient is to have a reasonable chance of having the diarrhea stopped, and have it go on to the benign, self-limited condition which Dr. Tedesco discussed. Both of them emphasized that early diagnosis and prompt treatment is critical in those cases."

c. Dr. Tedesco's finding of 10 per cent PMC incidence was valid and the only controlled study available at the time. Upjohn's President, Dr. Hubbard, testified at the Senate hearings on Cleocin in 1975 that the Tedesco studies were "determinative" and "I have no doubt of the validity of Dr. Tedesco's observations." (App. 241-42). Whether all such cases would develop into serious colitis depended on the promptness of diagnosis and treatment; and in any event, Dr. Tedesco definitely disputed and found totally unacceptable Upjohn's incidence estimate of 1 in 50,000 to 1 in 100,000 (App. 190).

d. Upjohn's estimate of serious colitis of 1:50,000 to 1:100,000 was based on voluntary reporting of such cases,

which was fraught with problems resulting in gross underreporting, making such an estimate extremely misleading. Voluntary reporting is discouraged by many factors including (1) feeling on the part of some physicians that it is not necessary to report; (2) assumption that similar complications have already been reported; (3) forgetfulness; (4) lack of time; (5) inconvenience; (6) lack of interest or awareness; (7) fear of becoming involved in litigation. (App. 413-14, cf. App. 158).

e. Respondents' implication that Upjohn discontinued promotion of the oral form of Cleocin after August, 1974 (Resp. Upjohn Br. p. 7) is not true and is contradicted by Upjohn's own advertisements which continued through October, 1974 (App. 551) after Upjohn had already come to the conclusion that oral Cleocin was not justified by the risk-benefit ratio.

f. The other studies referred to in Respondents' brief with a lesser reported incidence of colitis than Dr. Tedesco's study, do not impair the reliability of Dr. Tedesco's study. Dr. Milligan's figures, which are the lowest for the incidence of colitis, were the result of several factors which explain the difference: (1) dosages were lighter (App. 372); (2) the patients studied by Dr. Milligan were treated by cholestryamine, a specific effective remedy which it was one of the purposes of the study to test (App. 371-72); and (3) the patients in Dr. Milligan's study had only injected Clindamycin (Cleocin), which Dr. Tedesco had found has an incidence of PMC which is only 25% of that of oral clindamycin (App. 501).

CONCLUSION

The writ of certiorari should be granted and the case set for argument, after which the judgment of the Court of Appeals for the Fourth Circuit should be reversed.

Respectfully submitted,

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